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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,782

05/26/2005

Jorgen Rasmussen

PATRADE

6076

49801 7590 10/07/2008

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

10/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,782	Applicant(s) RASMUSSEN ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 10-13 is/are rejected.
- 7) ☒ Claim(s) 5, 9 and 14-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the Amendment filed 7/7/08. As directed by the amendment, the replacement drawing sheets amending Figures 1, 7-9, 13, 16, and 18 have been entered; the amendment to the specification has been entered and claims 1-16 have been amended. Claims 1-16 are pending in this application.

Drawings

2. The drawings are objected to because Lines, numbers & letters are not uniformly thick and well defined, clean, durable, and black (poor line quality). Moreover the numbers and reference characters are not plain and legible (particularly in figure 1). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification-New Matter

3. The amendment filed 7/7/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- "A" indicates the region corresponding to that in Figure 9 where a mechanism can be added to the lever 8 to transfer movement of the lever to a dose-counting mechanism. "B" indicates the region corresponding to that in Figure 8 where a secondary lever 39 attached to the canister 6 and a means 44 for translation of movement can be added to transfer movement of the canister to a dose-counting mechanism.
- "C" indicates the region above the wheel 30 that corresponds to Figure 9 as shown.
- Movement translation means 44 is also shown which can translate the motion of the lever 80 to a dose-counting mechanism, for example as shown in Figure 8.

These limitations were not previously described in the specification, they were not previously shown in any of the drawings, and they appear to be newly added subject matter to the specification and the drawings.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112-New Matter

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3 & 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the newly added amendment "wherein the cap no longer abuts the top of the pressurized canister or the means for engagement with the bottom end of the pressurized canister when the cap is in its open position" was not described in the specification.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1-3, 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna (5,692,492) as applied to claims 3 and 4 above, and further in view of Rand et al., (6,360,739).**

Regarding claim 1, Bruna teaches an inhaler device (Figure 14) for dispensing a medicament from a pressurized canister (1), where said inhaler device comprises a

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mouthpiece (5) arranged in a housing (21), where said housing (21) substantially encloses the pressurized canister (1), where a lever arm (6) is provided, where said lever arm (6) comprises means (91a and 91b) for engaging a bottom of the pressurized canister (1) such that said lever arm (6) may be activated by a user in order to dispense a dose, wherein the lever arm (6) further engages a yoke (7) where transfer of movement from said lever arm (6) due to activation of said lever arm to the yoke (7) is linear and/or non-linear.

Regarding claim 3, Bruna et al., teach an inhaler device (Figure 14) meeting the limitations when the claim is read in the alternative for the cap abutting means and when the lever can also be the cap. The Bruna et al., reference teaches an inhaler device for dispensing a medicament from a pressurized canister (1), where said canister (1) comprises a bottom and a top, and that a valve mechanism (2) is provided in the top of said canister (1) for dispensing a medicament and that in use the canister is placed with the top downwards proximate a mouthpiece (5), where the device comprises a mouthpiece (5) and a means for guiding and/or holding the canister (22), and a lever arm (6) comprising means (91a, 91b) for engagement with the bottom end of the canister (1), such that the canister (1) is not accessible from the outside, and further that a seat for engagement with the top of the canister (1) is provided inside the housing (38), and a cap (6) is pivotally arranged such that the cap (6) can be pivoted into a closed position where it covers the mouthpiece (5) and an open position where the mouthpiece (5) is accessible, and that said cap (6) further comprises means for abutting the top of the canister and/or for abutting the means (7) for engagement with the bottom

end of the canister (91a) when the cap (6) is in its closed position such that the canister (1) cannot be activated accidentally. See: col. 1, lines 4-8; col. 11, lines 1-43 and Figure 14.

Bruna et al., teach a device with a lever arm characterized in that the length of the lever arm (6) is such that when the cap (6) is closed the free end of the lever arm (6) is flush with or contained within the housing, and when the cap (6) is opened the free end of the lever arm (6) will project from the housing (21).

However, the Bruna et al., reference lacks yoke means for transferring movement to a dose counting mechanism arranged in the housing as claimed in claims 1-2, 6-8 and 10-13 and wherein the cap no longer abuts the top of the pressurized canister or the mean for engagement with the bottom end of the pressurized canister when the cap is in its open position as claimed in claim 3.

Rand et al., teach a metered dose inhaler with a counter that is actuated by the movement of the container relative to the housing, thus teaching the dose counting mechanism of claim 1.

The Rand et al., reference teaches that each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements. These movements are translated through the counter mechanism into appropriate movements of the digit wheels (33), one number on each of the printed circumferential faces of the digit wheels being clearly visible through the window (20) at the back of the housing (1), to indicate that a further dose of medicament has been dispensed. Thus, Rand et al teach the claim limitations of claim 8.

Rand et al., teach that the counter mechanism is small enough to be located to the sides of and behind the stem block molded in housing so as not to interfere with the aerosol fume as it emerges. See: col. 7, lines 50-54.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the inhaler device as taught by Bruna et al., by adding the dosage counter as taught by Rand et al., because of the reasonable expectation of obtaining a metered dose inhaler with a dose counter that would provide the user useful information regarding the remaining life of the inhaler product.

Regarding the limitation of claim 3, “wherein the cap no longer abuts the top of the pressurized canister or the means for engagement with the bottom end of the pressurized canister when the cap is in its open position” it would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed a separate cap and actuation lever since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Response to Arguments

8. Applicant's arguments filed 7/7/08 have been fully considered but they are not persuasive.

9. Applicant argues that Rand lacks a dose counting mechanism that utilizes a yoke. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

1986). Bruna teaches the yoke, which as defined by the Webster's new World Dictionary, Third College Edition, is "something that binds, unites, or connects" and Rand was used to teach a dose counter mechanism, which applicant admits "It is known in the art to incorporate dose counting devices in these types of devices." See: Response filed 7/7/08, last line of page 16 to first line of page 17. Moreover, applicant admits on page 12, lines 4-5 in the response filed 7/7/08 that "The dose counting mechanisms are generally interchangeable with minor mechanical modifications."

Therefore, it is clear that the incorporation of a dose counting mechanism taught by Rand into the inhaler device disclosed by Bruna is a modification that would be obvious to a skilled artisan.

Conclusion

10. Claims 4, 5, 9 & 14-16 are free of art but have other pending rejections and/or are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

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